
Stem Cell Agency Approves \$72 million to Accelerate Promising Projects Toward the Clinic

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San Francisco, CA – A faster path to clinical trials and an enhanced commitment to support industry developing the most promising therapies won approval at the March Board meeting of California's stem cell agency, the California Institute for Regenerative Medicine (CIRM).

The Board, more formally known as the Independent Citizens Oversight Committee (ICOC), voted to approve a new \$40 million Preclinical Development Award initiative. The goal of the award is to support projects that the agency is already funding, to help them with all the development activities needed to get a therapy ready for approval by the Food and Drug Administration (FDA). This includes developing plans to manufacture the stem cells needed for the therapy and doing the studies to show that these cells function as expected. The award also allowed for researchers not yet funded by the agency to apply, provided they can show they have co-funding from an outside company or organization.

"If a researcher or company has already identified a therapy or approach that shows potential in battling disease, we want to help them in every way we can," says Alan Trounson, Ph.D., President of the stem cell agency. "By helping them develop plans on manufacturing the therapy and how to ensure the quality of the product and what the best dosage will be we can really give them the tools they need to get this to the FDA and ultimately to patients in as short a time as possible.

The Board also voted to approve another round of funding for the Strategic Partnership initiative. The \$32 million allocated will go to companies who can either provide matching funds or show they have enough money on hand to match CIRM funding. The goal is develop a partnership with a company to move a treatment through Phase 1 or Phase 2 clinical trial within 3 years.

In addition the Board voted to make final the changes introduced following the Institute of Medicine report in December 2012. The report, while praising the agency as a "bold social innovation", raised questions about its governing structure saying it created the potential for a perception of conflicts of interest in how it funds research. The Board quickly adopted a sweeping series of reforms to address those concerns, and others, and voted to review those reforms one year later to see if they had been effective. Today the Board determined they had been extremely effective, and voted to make them permanent.

"The vote today shows the changes we introduced one year ago, though difficult, have succeeded in protecting the integrity of the Board and the integrity of the work we do and the way we do it," says Jonathan Thomas, J.D., Ph.D., Chairman of the Board, the Independent Citizens Oversight Committee (ICOC).

Those changes include:

- The 13 Board members appointed from institutions eligible for funding from the stem cell agency, such as those in the University of California system, no longer vote on any grants brought before the Board but would instead abstain
- All members of the Board are able to participate in discussions on applications but only patient advocates and independent members of the Board can vote on funding issues (members will continue to refrain from any discussion of specific applications from their institutions)
- Patient Advocates continue to be members of the Grants Working Groups but do not vote to recommend individual applications
- Programmatic review, aimed at balancing the agency's portfolio, takes place at public Board meetings where members have a chance to make changes to recommendations from the Grants Working Group
- Industry representatives are involved on the Grants Working Group, and also participate in a newly constituted Scientific Advisory Board

- Appeals on applications not recommended for funding are handled by science staff who will evaluate them, determine if they merit further review by the Grants Working Group, and ultimately make recommendations to the Board. Staff are also allowed to advocate for applications that they believe should be considered in programmatic review
- The Chair and President share a division of responsibilities with the President supervising all scientific operations and internal operational responsibilities. In addition the Grants Working Group reports to the President. The Chair handles the 'external affairs' aspect of the agency, things such as financial sustainability to raise additional funds, state legislative relations, bond financing, public communications etc.
- A Scientific Advisory Board has been created to provide the President counsel on such issues as funding priorities and portfolio strategy

"The Board took a bold step here in responding to the IOM recommendations," says Thomas, "and having seen it play out over the past year we should be happy at the way these changes have worked and even helped improve our process."

About CIRM: CIRM was established in November 2004 with the passage of Proposition 71, the California Stem Cell Research and Cures Act. The statewide ballot measure, which provided \$3 billion in funding for stem cell research at California universities and research institutions, was overwhelmingly approved by voters, and called for the establishment of an entity to make grants and provide loans for stem cell research, research facilities, and other vital research.

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